is an aqueous solution of netilmicin sulfate and one or more buffers, chelating agents, antioxidants, and preservatives. Each milliliter contains netilmicin sulfate equivalent to 10 milligrams, 25 milligrams, or 100 milligrams of netilmicin. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of netilmicin that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 3.5 and not more than 6.0. The netilmicin sulfate used conforms to the standards prescribed by § 444.46(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The netilmicin sulfate used in making the batch for potency, loss on drying, pH, residue on ignition, specific rotation, and identity.

(*b*) The batch for potency, sterility, pyrogens, and pH.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(*a*) The netilmicin sulfate used in making the batch: 12 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 12 immediate containers.

(*2*) For sterility testing: 20 immediate containers collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the product with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 0.1 microgram of netilmicin per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(a) of this chapter, using a solution containing 10 milligrams of netilmicin per milliliter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

[48 FR 18801, Apr. 26, 1983, as amended at 55 FR 11584, Mar. 29, 1990]

§ 444.262 Sisomicin sulfate injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sisomicin sulfate injection is an aqueous solution of sisomicin sulfate and one or more suitable buffers, chelating agents, and preservatives. Each milliliter contains sisomicin sulfate equivalent to 50 milligrams of sisomicin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of sisomicin that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 2.5 and not more than 5.5. The sisomicin sulfate used conforms to the standards prescribed by § 444.62(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The sisomicin sulfate used in making the batch for potency, loss on drying, pH, residue on ignition, specific rotation, and identity.

(*b*) The batch for potency, sterility, pyrogens, and pH.

(ii) Samples required:

(*a*) The sisomicin sulfate used in making the batch: 12 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 12 vials.

(*2*) For sterility testing: 20 immediate containers collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the product with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 0.1 microgram of sisomicin per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(a) of this chapter, using a solution containing 10 milligrams of sisomicin per milliliter.

(4) [Reserved]

(5) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

[46 FR 2989, Jan. 13, 1981, as amended at 50 FR 19919, May 13, 1985]

§ 444.270 Streptomycin sulfate injectable dosage forms.

§ 444.270a Sterile streptomycin sulfate.

The requirements for certification and the tests and methods of assay for sterile streptomycin sulfate, packaged for dispensing, are described in § 444.70a.

[42 FR 21275, Apr. 26, 1977]

§ 444.270b Streptomycin sulfate injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Streptomycin sulfate injection is an aqueous solution of streptomycin sulfate. It may contain one or more suitable and harmless preservatives, buffer substances and stabilizing agents. Each milliliter contains streptomycin sulfate equivalent to 400 milligrams, 420 milligrams, or 500 milligrams of streptomycin. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of streptomycin that it is represented to contain. It is sterile. It is nonpyrogenic. It contains no depressor substances. Its pH is not less than 5.0 and not more than 8.0. The streptomycin sulfate used conforms to the standards prescribed by § 444.70a(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain;

(i) Results of tests and assays on:

(*a*) The streptomycin sulfate used in making the batch for potency, depressor substances, loss on drying, pH, and identity.

(*b*) The batch for potency, sterility, pyrogens, depressor substances (except that the results of this test performed on the streptomycin sulfate used in making the batch may be submitted instead), and pH.

(ii) Samples required:

(*a*) The streptomycin sulfate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) If the batch is packaged for use in the manufacture of another drug:

(*i*) For all tests except sterility: Five containers, each containing not less than 2.0 milliliters.

(*ii*) For sterility testing: 20 containers, each containing not less than 2.0 milliliters.

(*2*) If the batch is packaged for dispensing:

(*i*) For all tests except sterility: A minimum of eight immediate containers.

(*ii*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and method of assay*—(1) *Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Using a suitable hypodermic syringe and needle, remove all of the withdrawable contents if it is represented as a single-dose container; or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Accurately dilute the portion with sterile distilled water to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with sterile distilled water to the reference concentration of 30 micrograms of streptomycin per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, using a solution containing 10 milligrams of streptomycin per milliliter.

(4) [Reserved]